

Application No.: 10/801,230
Reply to Office Action of: August 29, 2005

IN THE DRAWINGS

The attached sheet of drawings includes changes to Fig. 4. This sheet replaces the original sheet including Figs. 4 and 5.

Fig. 4 has been corrected to replace numbers "64" and "66" with "36A" and "36B", respectively. Figs. 4, 5, and 6 each show a cross-sectional side view of the same device, and the elements depicted in Fig. 4 as "64" and "66" are referred to in the specification at paragraph [0064], line 1, as "electrodes 36A, 36B." In Figs. 5 and 6, those same elements are labeled "36A" and "36B", respectively. Fig. 4 has been corrected to correspond to the language in the specification.

An annotated sheet showing changes to drawing Fig. 4 is attached hereto for the Examiner's convenience.

ATTACHMENTS: Replacement Sheet
Annotated Sheet Showing Changes

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REMARKS

In the specification, paragraphs [0004], [0049] and [0058] have been amended in accordance with the Examiner's suggestions.

With respect to Figure 19, paragraphs [0086] and [0087] of the specification has been amended to delete the reference number 121, which does not appear on the drawings. The number was intended to indicate the "distal end" of delivery device 120. Applicants submit that no reference number is necessary as a person of ordinary skill in the art reading the description of the invention would be able to determine which end of the delivery device shown in Fig. 19 is the distal end. Paragraph [0086] describes the placement of "device housing 106" in the distal end of the delivery device and Fig. 19 shows "device housing 106" within the delivery device 120 with a screw-like extension 118 extending out of the delivery device. In paragraph [0085] of the specification, the screw-like extension 118 is described as extending distally from the delivery device during placement of the stimulation device 105, thus, the distal end of the delivery device needs no specific identification.

Claims 1-56 are currently pending in this application. By this Amendment, claims 1, 3, 7, 12, 14, 25, 26, 27, 29, 31, 39, 41, 47, and 49 are amended and claims 9, 10, 11, 13, 28, 30, 45, 46, and 48 are cancelled.

§ 102 Rejection of the Claims

The Examiner rejected claims 1, 2, 6-11, 13, 15, 19-21, 24, 25, 27, 28, 30, 32, 34-36, 39-46, 48, 50-52, 55, and 56 under 35 U.S.C. § 102(e) as being anticipated by Swoyer et al., U.S. Patent No. 6,754,536. Applicants request reconsideration in light of the amendments to the claims and the following remarks.

Independent claims 1, 25 and 39 have been amended to more specifically describe the fixation structures used to attach the device housing to a surface within the gastrointestinal tract. Each of the fixation structures of the amended claims comprises an element that is either mounted on the device housing or at least partially contained within the device housing. The GI tract stimulator and/or monitor implantable medical device (IMD) described and claimed in Swoyer et al. includes an "elongated flexible member extending from the housing to an active fixation mechanism adapted to be fixed into the GI tract wall." Thus, the teachings of Swoyer et

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al. do not anticipate the claimed invention and Applicants respectfully request that the rejection under 102(e) be withdrawn.

The Examiner rejected claims 1, 2, 9-11, 13, 15-17, 20, 21, 24, 25, 28, 30, 32, 36, 39, 40, 45, 46, 48, 51, 52, 55 and 56 under 35 U.S.C. § 102(e) as being anticipated by Imran et al., U.S. Patent Publication No. US2004/0088023 A1. Applicants request reconsideration in light of the amendments to the claims and the following remarks.

Independent claims 1, 25 and 39 have been amended to more specifically describe the fixation structures used to attach the device housing to a surface within the gastrointestinal tract. Imran et al. do not describe fixation structures of the type described in the amended claims and therefore do not anticipate the claimed invention. Accordingly, Applicants respectfully request that the rejection under 102(e) be withdrawn.

§ 103 Rejection of the Claims

The Examiner rejected claims 3, 4 and 26 under 35 U.S.C. § 103(a) as being unpatentable over Swoyer et al., U.S. Patent No. 6,754,536, in view of Kilcoyne, U.S. Patent Publication No. US 2005/0043601 A1. Applicants disagree and request reconsideration in light of the amendments to the claims and the following remarks.

The Examiner takes the position that because the means of attachment described by Kilcoyne wherein such attachment means is directly on the device housing would allow the Kilcoyne device to be smaller that it would be obvious to one skilled in the art to modify the Swoyer et al. device to have the attachment device attached to the device housing. However, a key feature of the Swoyer et al. device is the "elongated flexible member extending from the housing to an active fixation mechanism." Modifying the Swoyer et al. device as the Examiner suggests would eliminate the need for the "elongated flexible member." Thus, the teachings of Swoyer et al. teach away from the idea of having the attachment device attached to the device housing.

Claim 5 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Swoyer et al., U.S. Patent No., 6,754,536, in view of Kilcoyne, U.S. Patent Publication No. US 2005/0043601 A1). Applicants disagree and request reconsideration in light of the amendments to the claims and the following remarks.

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The Examiner takes the position that Swoyer et al. teaches that the attachment means can be constructed to operate as electrode but does not teach that the attachment means may be a part of the housing but that Kilcoyne teaches that the attachment means may be a portion of the device housing. For the reasons set forth above, Swoyer et al. teaches away from having the attachment means a portion of the device housing as the use of the elongated member having the flexible bend to tether the stimulator to attachment means is a significant element of the Swoyer et al. device.

Claims 12, 29 and 47 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Swoyer et al., U.S. Patent No. 6,754,536, in view of Imran, U.S. Patent Publication No. US 2005/0090873 A1 ("Imran '05"), and as being unpatentable over Imran, U.S. Patent Publication No. US 2004/0088023 A1 ("Imran '04"), and further in view of Imran '05. Applicants disagree and request reconsideration in light of the amendments to the claims and the following remarks.

The Examiner takes the position that Imran '05 teaches holding stimulating electrodes in electrical contact with the wall of a portion of the gastrointestinal tract with a fixation device that comprises a self-expanding tubular member where Imran '04 and Swoyer et al. each show devices that use anchor mechanisms that puncture stomach tissue to hold the stimulator in place. The Examiner asserts that it would have been obvious to modify either the Swoyer et al. device or the device of Imran '04 in view of Imran '05 in order to implement a less invasive means of attaching the electrodes to the gastrointestinal wall.

The arguments regarding the non-obviousness of the claimed invention over Imran '04 and Swoyer et al. set forth above also apply here. Furthermore, the teachings of Swoyer et al. and Imran '04 teach away from using less invasive means for attaching electrodes to the gastrointestinal wall and in fact teach that in some embodiments the electrode should be embedded in the gastrointestinal wall or penetrate the wall. In Swoyer et al., at column 8, lines 61-65, a combined active fixation mechanism and stimulation/sense electrode is described to be "adapted to penetrate the mucosa." Similarly, in column 9, at lines, 18-20, a stimulation electrode is described that "can be a projection or pin that is pressed into or through the mucosa," Imran '04 provides for example, in paragraph [0014] that in a preferred embodiment, "at least one stimulating electrode is embedded in the wall of the stomach." Moreover, even if the fixation device of Imran '05 was used with the Swoyer or Imran '04 device, for the reasons discussed above, each of the claim limitations of the device and methods of the instant invention

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would not be met. Thus, the Examiner has failed to establish a prima facie case of obviousness and Applicants respectfully request that the rejection under 103(a) be withdrawn.

Claims 14, 31 and 49 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Swoyer et al., U.S. Patent No. 6,754,536, in view of Somdahl, et al., U.S. Patent No. 6,445,948. Applicants disagree and request reconsideration in light of the amendments to the claims and the following remarks.

As discussed above, Swoyer et al. does not teach a fixation structure mounted on or contained within the device housing of a stimulation device and in fact a main feature of the Swoyer et al. device is an elongated member tethering the pulse generator to an active fixation mechanism. Thus, the Examiner has failed to establish a prima facie case of obviousness and Applicants respectfully request that the rejection under 103(a) be withdrawn.

Claims 22, 23, 37 and 38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Swoyer et al., U.S. Patent No. 6,754,536, and Imran, U.S. Patent Publication No. US 2004/0088023 A1. Applicants disagree and request reconsideration in light of the amendments to the claims and the following remarks.

The arguments regarding the non-obviousness of the claimed invention over Imran '04 and Swoyer et al. set forth above also apply here.

Claims 18 and 33 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Swoyer et al., U.S. Patent No. 6,754,536, and as being unpatentable over Imran, U.S. Patent Publication No. US 2004/0088023 A1. Applicants disagree and request reconsideration in light of the amendments to the claims and the following remarks.

The arguments regarding the non-obviousness of the claimed invention over Imran '04 and Swoyer et al. set forth above also apply here.

Obviousness Double Patenting

Claims 1, 2-5, 7, 8, 9, 10, 11, 13, 14, 15, 19, 25-27, 30, 31, 32, 34, 35, 36, 37, 38, 39, 45 and 46 have been rejected under the doctrine of obviousness-type double patenting over claims 1, 3, and 12 of U.S. Patent No., 6,754,536. Applicants request reconsideration in light of the amendments to the claims and the following remarks.

As discussed above, independent claims 1, 25 and 39 have been amended to more specifically describe the fixation structures used to attach the device housing to a surface within the gastrointestinal tract. Each of the fixation structures of the amended claims comprises an

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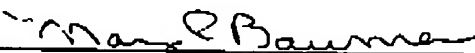
element that is either mounted on the device housing or at least partially contained within the device housing. The GI tract stimulator and/or monitor implantable medical device (IMD) claimed in Swoyer et al. includes an elongated flexible member extending from the housing to an active fixation mechanism. Modifying the Swoyer et al. device to eliminate the elongated flexible member would substantially change the device, thus, Applicants respectfully submit that the devices and methods of the claims are not obvious over the teachings or claims of Swoyer et al.

The Examiner is respectfully requested to contact the undersigned by telephone at 763.505.0003 or by E-mail at mary.p.bauman@medtronic.com with any questions or comments.

Please grant any extension of time necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

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TITLE: ~~F. A LUMINAL DEVICE FOR GASTROINTESTINAL~~ CRITICAL
STIMULA ~~ON~~
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Annotated Sheet

